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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,552	05/17/2005	Lak Shin Jeong	234937	7628

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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/530,552

Applicant(s)

JEONG ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,19-31 and 43-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43,44 and 49-51 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,8,10,19,20,22,24,26-31 and 45-48 is/are rejected.
- 7) ☒ Claim(s) 5,7,9,21,23 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>5/8/06</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The Rejections under 35 USC § 102 have been overcome with the amendments to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8, 22, 24, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 appears to be identical to claim 6. Applicants indicate that these are not, but the actual claim language does not reflect their intent, rendering the claims indefinite. Applicants state that Claim 8 is the alpha-anomer and claim 6 is the beta, but the claim language does not convey this. First, the thio-sugar rings are depicted exactly the same (i.e. superimposable) in both claims, and thus one of ordinary skill in the art is not obliged to read them as being any different. The sole difference between III in claim 6 and IV in claim 8 is that one purine ring is the mirror image of the other. However, this is of no significance, since the purine ring is not chiral. If applicants intend these sugar rings to be different, they must be drawn as different. One of ordinary skill in the art is not going to

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infer that the sugar rings are different on the basis of the purine rings being drawn differently.

Claims 1, 3-4, 6, 8, 10, 19-20, 22, 26-28, 30, 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The replacement of “thio” with “mercapto” is deemed to be new matter. Applicants make the unsupported assertion that it “is clear” that mercapto was intended, but present no reasoning whatsoever that would point to such conclusion. Applicants give no reason why this could not have been e.g. methylthio or acylthio, choices that, unlike “mercapto” actually do have the letters “thio”.

Claims 26-31, 45, 48, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claim 49 species, does not reasonably provide enablement for other species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The rejection was given previously in general. Applicants present testing on one species, compound 33 (LJ-529), showing it effective in two xenograft models of breast cancer. This species cannot be deemed representative of the genus as a whole. First, it is of the type III, making it an A3-agonists, whereas compounds of the type II are A3 antagonists, according to the specification, paragraph 0133. Second, it has significant structural features, most importantly the aralkyl group attached the amine, the

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carboxamide substituent, and the thiosugar, features which other compounds do not necessarily have. Thus, for example, the claim 46 genus does not have the thiosugar, the first claim 7 species, and the claim 9 species both lack the amide, and the claim 43 species lacks the aralkyl. In fact, paragraph 0133 specifically states that compound 33 “exhibited the most strong and most selective A3 agonist activity”, and hence this species cannot be considered representative of the genus as a whole.

Claim Objections

Claims 5, 7, 9, 21, 23, 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Foreign Priority

Applicants have claimed benefit in the PCT application of REPUBLIC OF KOREA 2002/0065441 10/25/2002, but no copy of this document has been received, nor does it appear on the oath. Clarification is invited.


Applicants have sent in a receipt for the Foreign Priority papers, but the examiner has not been able to locate them. The PCT/US03/33987 file was checked but did not have the papers. The EPO website for the international application had the US provisional papers, but not the RoK papers. It appears that the USPTO has misplaced these papers, and a copy needs to be sent in to replace the missing document.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Mark L. Berch
Primary Examiner
Art Unit 1624

6/16/06